

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Karen Forester, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-00486

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Lee Congleton III, M.D.)

Pending before the court is the Motion to Exclude Case-Specific Opinions and Testimony of Lee Congleton III, M.D. [ECF No. 89] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file general causation *Daubert* motions in the main MDL and specific causation *Daubert* motions, responses, and replies in the individual member cases. To the extent that an expert is both a general and specific causation expert, the parties were advised that that they could file a general causation motion in the main MDL 2327 and a specific causation motion in an individual member case. PTO No. 217, at 4.

II. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that plaintiffs may use “a reliable differential diagnosis[, which] provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. at 262 (citations omitted).

Defendants, however, need not conduct a differential diagnosis to identify the specific cause of an injury because they do not bear the burden of proving causation. *See* 3 David Faigman et al. *Modern Sci. Evidence* § 21:6 (2015-2016 ed.). Indeed, a defendant’s specific causation expert’s testimony should not be excluded because it fails to identify the specific cause of a plaintiff’s injury. *See Yang v. Smith*, 728 S.E.2d 794, 800 (Ga. Ct. App. 2012) (refusing to exclude defendant’s specific causation expert

testimony where that testimony did not identify an injury's specific cause because the defendant had no burden to prove the specific cause of the injury). In lieu of conducting traditional differential diagnoses, defendants may instead provide expert testimony suggesting alternative causes for the plaintiff's injury in order to rebut the plaintiff's specific causation testimony. *See Westberry*, 178 F.3d at 265 ("The alternative causes suggested by a defendant 'affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony,' unless the expert can offer '*no* explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause.'" (citations omitted)); *see also* Faigman, *supra*, at § 21:4 ("Sometimes, the courts subtly shift the burden of production onto the defendant when determining whether the [plaintiff's] expert has done a sufficient job in ruling out other causes.").

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

The plaintiffs first argue that Dr. Congleton did not conduct a proper differential diagnosis. However, as a defense specific causation witness, Dr. Congleton need not conduct a differential diagnosis. Instead, he is tasked with giving testimony that affects the weight and potentially the admissibility of the plaintiffs' specific causation expert. So long as the defense specific causation expert's opinion is a product of his specialized knowledge or training and is reliably grounded, it should be admissible to rebut the plaintiffs' specific causation expert.

Here, Dr. Congleton is a board-certified urologist, who has performed over 2,000 surgeries to correct SUI and over 500 surgeries using the TVT-O sling. Resp. 2–3 [ECF No. 99]. Dr. Congleton’s expert report and deposition testimony show that he conducted a detailed review of the plaintiffs’ medical records and performed a physical examination of the Ms. Forester. Dr. Congleton conducted a thorough, reliably-grounded analysis of the medical evidence and determined that the plaintiff’s proffered specific cause was unlikely. He need not take an additional step and prove that another alternative cause caused the plaintiffs’ injury; causation is the plaintiffs’ burden. To the extent the plaintiffs believe that Dr. Congleton’s testimony is flawed, they may address those issues on cross-examination and with the testimony of their own specific causation witness. The plaintiffs’ Motion on this point is **DENIED**.

Next, the plaintiffs argue that I should exclude Dr. Congleton’s testimony regarding the frequency of dyspareunia following sling surgeries, degradation, contraction, deformation, cytotoxicity, design, and the sufficiency of Ethicon’s instructions for use. However, those topics are the provinces of a general causation expert—not a specific causation expert. In PTO No. 217, I directed the parties to file general causation objections in the main MDL. Because the plaintiffs failed to do so here, their Motion on this point is **DENIED**.

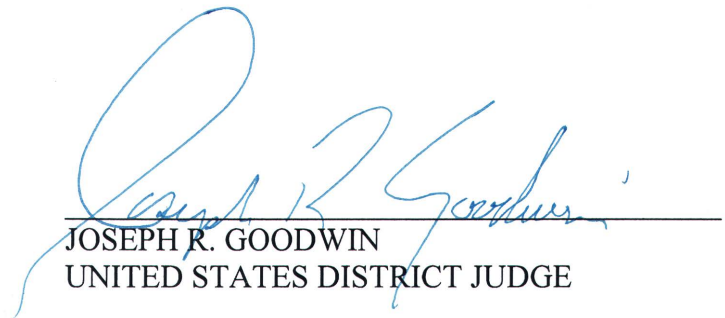
Finally, the plaintiffs object to a number of issues in a “miscellaneous” section. However, they offer only cursory arguments on these points and reference the record only minimally. It is inappropriate to rule on these issues at this time. The plaintiffs’ Motion on this point is **DENIED**, and any remaining issues are **RESERVED** for trial.

IV. Conclusion

The court **ORDERS** that the Motion to Exclude Case-Specific Opinions and Testimony of Lee Congleton III, M.D. [ECF No. 89] is **DENIED in part** and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 6, 2017



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE